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IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF ARKANSAS

MELANIE THIGPEN, an individual,

Plaintiff,

v.

C.R. BARD, INC., a New Jersey corporation; BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, and DOES 1 through 10,

Defendants.

Case No. 4:20-CV-1087-LPR

COMPLAINT

(JURY TRIAL DEMANDED)

This case assigned to District Judge Rudofsky and to Magistrate Judge Harris

Plaintiff, Melanie Thigpen, alleges for her Complaint against the Defendants as follows:

INTRODUCTORY ALLEGATIONS

1. This is a product-liability action against Defendants arising out of the malfunction and resulting injuries to Plaintiff from a Bard G2 inferior vena cava ("IVC") filter (the "Filter") that was implanted in Plaintiff on or about August 29, 2006, at Baptist Memorial Hospital in Memphis, Tennessee.

2. An IVC filter is an implantable medical device that is placed in the IVC—the body's largest vein that carries blood to the heart and lungs—purportedly to catch blood clots before they reach the heart and lungs.

3. In the early 2000s, Defendant Bard Peripheral Vascular (collectively with Defendant C.R. Bard, Inc. "Bard") was one of several manufacturers in the IVC

filter market that saw an opportunity to expand the existing market and to increase its own share of that market by developing an IVC filter that could be retrieved after implantation. Prior to that time, IVC filters were permanent-only devices, implanted for the lifetime of a patient and not capable of removal without major surgery. The existing, permanent devices were designed to be sturdy so they could be permanently implanted in a patient's IVC without tilting, migrating, or breaking. Bard sold a permanent IVC filter called the Simon Nitinol Filter ("SNF") that, like most permanent filters, had a long history of extremely low complication rates.

4. Bard believed that it could Bard substantially increase its share of the U.S. IVC filter market and, thus, its profits by introducing a retrievable filter. Bard knew that other competing medical device manufacturers were also working on retrievable IVC filters, and the company that would win the race to the market by introducing its product first would reap most of the rewards. Bard concluded that it could overcome the "absence of solid clinical history" for its new retrievable filter through "aggressive marketing." And, as a result, it began to design and develop an IVC filter that could be retrieved after implant.

5. To win the race to market, Bard took shortcuts in both (1) designing and testing of its permanent-but-retrievable IVC filters and (2) obtaining regulatory clearance from the FDA to sell the filter. Significantly, though Bard marketed and sold its retrievable filters as permanent devices that could be safely retrieved after implant, Bard never designed or tested the filters for permanent implantation. For its first-generation device, the Recovery filter, Bard conducted a single human clinical trial that was not a safety or effectiveness study; rather, it was a short-term study as to whether the device could be safely retrieved shortly after implantation. For its second-generation device, the G2 (originally named the Recovery G2), Bard conducted a 100-patient retrievability study. Both studies demonstrated significant incidence of device malfunctions, including a fracture and migration of the Recovery in just 33 patients; in the G2 study, Bard learned that the filter was tilting, perforating,

and migrating at rates significantly higher than expected and significantly higher than Bard's predicate device for the retrievable filters: the SNF. Despite these results, Bard never did any studies nor any trials of the filters to determine if they were safe and effective as a permanent filter. Bard did not call off its release of the filters; instead, Bard charged forward and sold the filter to doctors and patients across the country, including Plaintiff. Significantly, Bard sold the filters as "permanent" devices with the "option" of retrieval—representing first and foremost that the devices were safe to be implanted for a lifetime.

6. To be able to sell the filters, Bard made misrepresentations to the FDA to obtain "clearance" for the sale of the filter. Clearance comes under the FDA's far less restrictive 510(k) process—a streamlined path in which a company represents that its product is so substantially similar to a product that has already been approved by the FDA to be on the market (substantially equivalent) that there is no need to fully vet and test whether the product is safe and effective. Bard promised the FDA that its new retrievable filter was "substantially equivalent" to the SNF, and that the filter was just as safe and effective when permanently left in the human body. But Bard had absolutely no proof that was the case. Indeed, its actual testing of its filters demonstrated precisely to the contrary.

7. Unsurprisingly, almost immediately, patients began experiencing major complications with Bard's retrievable filter—it was breaking/fracturing and migrating to the heart at rates not previously seen with IVC filters. In the first 10 months after full market release, there were nine patient deaths from Bard's Recovery filter. Bard was unable to determine the root cause for those deaths, but, rather than pull the product from the market, it continued to market and sell the filter to doctors and patients, assuring them that there was no real problem, while at the same time forming a team to respond to what it called a crisis.

8. Further, Bard found that the filter was failing and causing death at rates many times higher than other IVC filters, including its own SNF, the predicate

device. Still, Bard did not pull the filter from the market. Rather, while it continued to sell the Recovery and without understanding why the Recovery was failing at such high rates, Bard designed a second generation (G2) filter on the fly. And, again, rather than test its safety and efficacy (particularly as a permanent device), Bard sold that second-generation filter to doctors and patients with little to no idea how it would perform long term. As a result, the G2 created new problems and risks for patients. By 2006, just months after release, an internal investigation at Bard determined the G2 had an "unacceptable risk" of complications. But Bard did not recall or place a hold on the product, warn doctors and patients of what it knew internally about the dangers of the device, nor take any action to protect people like Plaintiff.

9. In subsequent generations, Bard (a) added a hook (G2X), (b) polished the filter and changed its name to "avoid baggage" (Eclipse), and (c) added caudal anchors (Meridian). It made these changes to hold its market share, while looking at new ways to design a safer IVC filter. But none of these minor changes fixed the significant problems with the filter.

10. At the same time, Bard developed another version of the filter that it called the Denali, which retained the essential design elements of all the iterations of its permanent-but-retrievable IVC filters.

11. Bard defectively designed the Filter because its risks outweigh its benefits and it fails to meet the reasonable expectations of consumers. Indeed, developing science suggests that all IVC filters, including the Filter, provide no benefit whatsoever to patients. The design choices that Bard made in designing all of its permanent-but-retrievable filters, including the Filter, rendered the filter defectively designed. There are reasonable alternative designs of IVC filters both on the market and that include additional safety features, such as design elements to reduce the risk of fracture and improvements to the anchoring mechanism to prevent tilting, movement (migration), and perforation, all failure modes that also increase the risk of fracture. Bard was similarly negligent in its design of the Filter.

12. Further, Bard failed to provide adequate warnings regarding the risks of all of its permanent-but retrievable filters, including the Filter. Bard knew that the Filter presented significantly increased risks of failures, including fracture, migration, tilt, and perforation as compared to other available IVC filters, including its own SNF. Nonetheless, it failed to warn doctors and patients of these significantly increased risks and the risks specific to its IVC filters. Still, Bard actively marketed the Filter as being safer than or at least as safe as other devices. Bard was similarly negligent in its warnings and failure to provide adequate warnings regarding the Filter.

13. Bard was negligent in their testing of the Filter prior to release. Bard failed to conduct worst-case scenario testing as required by standards of reasonable engineering and the federal Food and Drug Administration ("FDA") guidance documents.

14. Bard was negligent in its post-market monitoring of the Filter because it was aware that the risks posed by the device exceeded the burden of taking available safety measures that would have reduced the risk of harm. These safety measures include the failure to warn and the failure to incorporate additional safety features.

15. Bard was negligent in failing to recall or to stop marketing the Filter once it realized that its IVC filters were not performing as expected, and the Filter was significantly more likely to fail and cause injury than other available devices. The filters risks exceeded their benefits, and they were not the substantial equivalent of the predicate device—Bard's own SNF filter.

16. Bard also engaged in fraud, deceit and concealment in that Bard knowingly misrepresented the benefits of the Filter by concealing and downplaying the risks so as to maintain sales and stock prices, and to keep consumers and victims like the Plaintiff ignorant of the defect in the Filter. Despite knowing that the Filter was substantially more likely to fracture, migrate, tilt, and cause death than other

filters, Bard marketed the filter as being safer and more effective than all other filters. Despite information demonstrating a lack of safety and efficacy, Bard failed to warn Plaintiff or physicians that the device should be promptly removed after the acute risk of clotting passed.

17. Bard misrepresented the safety and effectiveness of its permanent-but-retrievable IVC filters, including the Filter. Bard sold all of its IVC filters as permanent devices; specifically identifying each filter as indicated for use "via permanent placement" in the IVC. But, Bard did not do adequate testing to ensure that the filters were safe for permanent implantation in the human body; and Bard knew, from the testing it did perform, that its permanent-but-retrievable filters were not the substantial equivalent of, and not as safe as, its permanent-only filter, the SNF.

18. Here, Plaintiff has suffered damages as a result of Bard's actions. In particular, Plaintiff's filter is perforating the IVC and impinges on the and more than likely perforate the posterior wall of the aorta, impinges on the underlying L3-4 disc and more likely than not perforates the gonadal vein. As a result, Plaintiff has suffered pain, emotional distress, and loss of enjoyment of life. As a direct and proximate result of these malfunctions and Bard's actions, Plaintiff suffered significant injuries and damages and required extensive medical care and treatment. As a further proximate result, Plaintiff has suffered and will continue to suffer significant medical expenses and pain and suffering, along with other damages.

PARTIES

19. Plaintiff Melanie Thigpen, (hereinafter "Plaintiff" or "Thigpen") is a citizen of and resident in the City of Truman, Arkansas.

20. Defendant C.R. Bard, Inc. ("CR Bard") is a corporation duly organized and existing under the laws of the state of Delaware and has its principal place of business in New Jersey.

21. Bard, at all times relevant to this action, designed, set specifications for, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold its permanent but retrievable filters, including the Filter, to be implanted in patients throughout the United States, including Arkansas.

22. Defendant Bard Peripheral Vascular, Inc. ("BPV") is a wholly owned subsidiary corporation of Defendant Bard, with its principal place of business at 1625 West Third Street, Tempe, Arizona.

23. BPV, at all times relevant to this action, designed, set specifications for, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold its permanent but retrievable filters, including the Filter, to be implanted in patients throughout the United States, including Arkansas.

24. Plaintiff is informed and believes, and thereon alleges, that at all times herein mentioned, each of the Defendants were the agent, servant, employee and/or joint venturer of the other co-Defendants, and each of them, and at all said times each Defendant was acting in the full course, scope, and authority of said agency, service, employment and/or joint venture.

25. Plaintiff is informed and believes, and thereon alleges, that at all times mentioned herein, Defendants, and each of them, were also known as, formerly known as, and/or were the successors and/or predecessors in interest/business/product line/or a portion thereof, assigns, a parent, a subsidiary (wholly or partially owned by, or the whole or partial owner), affiliate, partner, co-venturer, merged company, alter egos, agents, equitable trustees and/or fiduciaries of and/or were members in an entity or entities engaged in the funding, researching, studying, manufacturing, fabricating, designing, developing, labeling, assembling, distributing, supplying, leasing, buying, offering for sale, selling, inspecting, servicing, contracting others for marketing, warranting, rebranding, manufacturing for others, packaging, and advertising the Filter.

26. Defendants, and each of them, are liable for the acts, omissions and tortious conduct of their successors and/or predecessors in interest/business/product line/or a portion thereof, assigns, parent, subsidiary, affiliate, partner, co-venturer, merged company, alter ego, agent, equitable trustee, fiduciary and/or their alternate entities in that Defendants, and each of them, enjoy the goodwill originally attached to each such alternate entity, acquired the assets or product line (or a portion thereof), and in that there has been a virtual destruction of Plaintiff's remedy against each such alternate entity, and that each such Defendant has the ability to assume the risk-spreading role of each such alternate entity.

27. Plaintiff is informed and believes, and thereon alleges that, at all times herein mentioned, Defendants, and each of them, were and are authorized to do and are doing business in the State of Arkansas and regularly conducted business in the State of Arkansas.

28. Upon information and belief, at all relevant times, Defendants, and each of them, were engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce and into the State of Arkansas, either directly or indirectly through third parties or related entities, its products, including the Filter.

29. At all relevant times, Defendants, and each of them, conducted regular and sustained business and engaged in substantial commerce and business activity in the State of Arkansas, which included but was not limited to researching, developing, selling, marketing, and distributing their products, including the Filter, in the State of Arkansas.

30. Upon information and belief, at all relevant times, Defendants, and each of them, expected or should have expected that their acts would have consequences within the United States including in the State of Arkansas, and said Defendants derived and continue to derive substantial revenue therefrom.

JURISDICTION AND VENUE

31. Plaintiff has suffered damages in an amount that exceeds the minimum jurisdictional limits of this Court. In particular, Plaintiff has suffered bodily injury as set forth below and has incurred pain and suffering. Plaintiff further seeks punitive damages against Defendants based on their conduct at issue in this suit.

32. This Court has jurisdiction over this case because Defendants committed acts in this jurisdiction giving rise to the claims that are the subject of this action.

33. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the event or omissions giving rise to the claim occurred in this District.

GENERAL ALLEGATIONS

Inferior Vena Cava Filters Generally

34. IVC filters first came on to the medical market in the 1960s. Over the years, medical device manufacturers have introduced several different designs of IVC filters.

35. An IVC filter is a device that is intended to filter or "catch" blood clots that travel from the lower portions of the body to the heart and lungs. IVC filters are designed to be implanted, either permanently or temporarily, in the IVC.

36. The IVC is a vein that returns blood to the heart and lungs from the lower portions of the body. In certain people, for various reasons, blood clots travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. Oftentimes, these blood clots develop in the deep leg veins, a condition called "deep vein thrombosis" or "DVT." Once blood clots reach the lungs, they are considered "pulmonary emboli" or "PE." Pulmonary emboli present risks to human health.

37. People at risk for DVT/PE can undergo medical treatment to manage the risk. For example, a doctor may prescribe medications like Heparin, Warfarin, or Lovenox to regulate the clotting factor of the blood. In some people who are at

high risk for DVT/PE, or who cannot manage their conditions with medications, physicians may recommend surgically implanting an IVC filter to prevent thromboembolitic events.

38. The first IVC filters sold were permanent filters. These devices were designed to be left in a patient's IVC permanently and have long-term follow-up data (of up to 20 years and longer) demonstrating their risks and the frequency of occurrence of such risks, which is relatively low.

39. Beginning in 2003, manufacturers also began marketing what are known as "optional" or "retrievable" filters. These filters were designed so that, in theory, they can be surgically removed from a patient after implantation, presumably after the risk of PE has subsided. These optional or retrievable filters are sold as permanent filters with an option to remove them, in some cases within a window; in the case of Bard's filters, it claims there is no window limiting retrieval.

40. But, while Bard sells its "retrievable" filters as permanent devices with unlimited retrieval windows, Bard never designed or properly tested the filters for safety as permanent devices and, over time, they demonstrate both a significantly increased risk of failure and becoming irretrievable.

41. Years after the implantation of retrievable filters into the bodies of patients, scientists began to study the effectiveness of the retrievable filters - studies that Bard itself had never done before placing the product on the market. In October 2015, an expansive article published in the Annals of Surgery concerning trauma patients inserted with IVC filters concluded that IVC filters were not effective in preventing pulmonary emboli, and instead actually caused thrombi to occur.

42. Comparing the results of over 30,000 trauma patients who had not received IVC filters with those who had received them, the Annals of Surgery study published its alarming results:

43. Almost twice the percentage of patients with IVC filters in the study died compared to those that had not received them.

- Over five times the relative number of patients with IVC filters developed DVTs.
- Over four times the relative percentage of patients with filters developed thromboemboli.
- Over twice the percentage of patients developed a pulmonary embolus – the very condition Bard told the FDA, physicians, and the public that its IVC Filters were designed to prevent.

44. This Annals of Surgery study- and many others referenced by it- now shows without any question that IVC filters in general are not only utterly ineffective but that they are themselves a health hazard.

45. On July 13, 2015, the FDA sent a warning letter to the Defendants stating that Defendants failed… "to establish and maintain procedures for receiving, reviewing, and evaluating complaints as required by 21 CFR 820. 198(a). Your current procedures governing complaint investigation activities at your facilities, CQA-STD-24 Standard for Product Complaint Handling Rev. 11 and CQA-STD-55, Standard for Complaint Investigation Process Rev. 01, MP9113, Complaint Investigation Activity Rev. 40, SOPQOI53100, BPV Complaint Handling System, Rev. 18, and SOPQ0700200, Complaint Investigation Procedures, Rev. 15 do not ensure product complaints are adequately evaluated."[1]

46. On July 19, 2019, another study published in the New England Journal of Medicine, of the effectiveness of all retrievable filters was conducted concerning 240 severely injured patients, the study concluded that placement of vena cava filters after major trauma did not result in a lower incident rate of pulmonary embolism than those who did not have a filter implanted.

47. The study used both Cook and Bard IVC filters, 117 patients received Bard Denali filters, and 5 received Cook retrievable filters. The Denali filter is substantially similar in design to the G2X filter because every retrievable filter

[1] Curse, Alona E., FDA Los Angeles District Director, FDA Warning Letter (13 July 2015).

marketed by Bard is based on the previously designed filter. Denali is the latest model based on the original 510k clearance of Bard's first retrievable filter model, the Recovery filter and was not cleared by the FDA by premarket approval. The study was published with its results, including the following:

- An entrapped thrombus was found within the filter in almost 5% of the patients
- Placement of the filter (within 72 hours after injury) did not result in a lower rate of pulmonary embolisms or death at 90 days which again is the very condition Bard told the FDA, physicians, and the public its filters were designed to prevent including the G2 and Meridian filter.

48. Early prophylactic placement of a vena cava filter after major trauma did not result in a lower incidence of symptomatic pulmonary embolism or death at 90 days than no placement of a filter.[2]

49. The G2X is manufactured by Bard and BPV is an example of a retrievable filter.

50. Since each of Bard's filter designs 510k clearance are based on its predecessors it is important to show below the history of Bard's retrievable IVC filters and its consistent lack of efficacy and the likelihood of failure and injury.

The Recovery Filter

51. In the early 2000s, Bard began development of its first generation "retrievable" filter, called the Recovery filter (hereafter "Recovery" or "Recovery Filter").

52. The Recovery Filter consists of two (2) levels of six (6) radially distributed Nitinol struts that are designed to anchor the filter into the inferior vena

[2] Kwok M. Ho, Ph.D., Sudhakar Rao, F.R.A.C.S., Stephen Honeybul, F.R.A.C.S., Rene Zellweger, F.R.A.C.S., Bradley Wibrow, F.C.I.C.M., Jeffrey Lipman, F.C.I.C.M., Anthony Holley, F.C.I.C.M., Alan Kop, Ph.D., Elizabeth Geelhoed, Ph.D., Tomas Corcoran, F.C.I.C.M., Philip Misur, F.R.A.N.Z.C.R., Cyrus Edibam, F.C.I.C.M., "A Multicenter Trial of Vena Cava Filters in Severely Injured Patients" N Engl J Med 381:328-337 (2019).

cava and to catch any embolizing clots. There are six short struts, which are commonly referred to as the arms, and six long struts, which are commonly referred to as the legs. Each strut is held together by a single connection to a cap located at the top of the device. According to the Patent filed for this device, the short struts are primarily for "centering" or "positioning" with the vena cava, and the long struts with attached hooks are designed primarily to prevent the device from migrating in response to "normal respiratory movement" or "pulmonary embolism."

53. The Recovery filter is made out of "Nitinol", an acronym for Nickel Titanium Naval Ordinance Laboratory. "Nitinol" possesses "shape memory," meaning it will change shape according to changes in temperature, and then, retake its prior shape after returning to its initial temperature. When placed in saline, therefore, the Nitinol struts become soft and can be straightened to allow delivery through a small diameter catheter. The metal struts then reassume their original shape when warmed to body temperature in the vena cava.

54. An IVC filter is typically implanted in the IVC via a catheter that is guided by a physician (normally an interventional radiologist) through a blood vessel into the IVC. The implanting physician normally reviews an imaging study prior to placement to determine size of IVC, renal vein location, and to identify any venous anomalies or clots in the vena cava. Following placement, the physician will normally use an imaging study to confirm successful placement. The Recovery filter was designed to be retrieved in a similar fashion.

55. In its design and development stage, Bard conducted a small clinical trial (involving human patients) to evaluate the retrievability of the Recovery filter. In a short-term setting involving less than 40 patients, the Recovery filter experience three significant failures: the first was that a filter moved substantially (migrated) from it location of implant toward the patient's heart; the second was that one filter broke (fractured) in two different places, resulting in pieces of the filter breaking apart and separating from the filter so that they could freely travel to the heart.

Despite those problems, Bard took no action to redesign the filter or to stop the process toward sale.

56. In 2002, Bard submitted a notification of intent to the FDA to market the "Recovery Filter System" for the prevention of recurrent pulmonary embolism by placement in the IVC.[3] Bard identified the SNF as one of the Recovery's predicate devices, representing to the FDA that the Recovery was the substantial equivalent in terms of safety performance and efficacy as the SNF. On November 27, 2002, the FDA cleared the Recovery filter for marketing and use in the prevention of recurrent pulmonary embolism via *permanent* placement in the vena cava in the following situations:

a. Pulmonary thromboembolism when anticoagulants are contraindicated;

b. Failure of anticoagulant therapy for thromboembolic disease;

c. Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced;

d. Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

57. In April 2003, Bard and BPV submitted a Section 510(k) premarket notification of intent to market the Recovery Filter for the additional intended use of *optional retrieval*. The FDA cleared this additional intended use on July 25, 2003.

58. Bard and BPV began actually marketing the device in April 2003, but full market release did not occur until January 2004.

[3] Bard submitted the notification under Section 510(k) of the United States Food, Drug and Cosmetic Act ("Act") of 1976 (21 U.S.C. 321 *et seq.*). The 510(k)-review process requires any entity engaged in the design, manufacture, distribution or marketing of a device intended for human use to notify the FDA 90 days before it intends to market the device and to establish that the device is substantially equivalent to a legally marketed predicate device. (21 C.F.R. §§ 807.81, 807.92(a)(3).) Substantial equivalence means that the new device has the same intended use and technological characteristics as the predicate device. This approval process allows a manufacturer to bypass the rigorous safety scrutiny required by the pre-market approval process.

59. Prior to full market release, Bard failed to adequately test the Recovery filter for safety as a permanent filter. In particular, it failed to test the filter to determine that it was reasonably safe under foreseeable worst-case scenario conditions, including how likely it was that the filter would tilt and what would happen to the filter if it were tilted.

60. Further, Bard's lab tests to simulate migration resistance consistently demonstrated that the Recovery was the worst IVC filter available at resisting migration and significantly worse than the SNF. Thus, contrary to Bard's representation to the FDA, the Recovery was not the substantial equivalent of that device.

61. Moreover, after an internal special design review committee raised questions as to the safety of the Recovery, and particularly its ability to resist migration, in December 2003, Bard did not stop its full market release of the filter or even answer the significant safety questions raised by the committee prior to release. Rather, Bard proceeded to full market release and conducted some (but not all) of the requested testing after the product was already one the market. And, then, the Recovery failed the tests, failing to meet the safety threshold that Bard established for migration resistance.

62. Shortly after full market release, Bard began receiving reports of significant filter failures, including migrations to the heart and deaths.

63. The Recovery Filter is prone to an unreasonably high risk of failure and patient injury following placement in the human body. Multiple studies report Bard's Recovery Filter to have a fracture and migration rate ranging from 21% to 31.7%.[4] When such failures occur, shards of the device or the entire device can travel to the heart, as seen here, where it can cause cardiac tamponade, perforation of the atrial

[4] *See e.g.,* Hull JE, Robertson SW. Bard Recovery Filter: Evaluation and Management of Vena Cava Limb Perforation, Fracture and Migration. *J Vasc Interv Radiol.* 2009;20(1):52-60; Nicholson W, *et al.* Prevalence of Fracture and Fragment Embolization of the Bard Recovery and Bard G2 Cava Filters and Clinical Implications Including Cardiac Perforation and Tamponade. *Arch. Int. Med.* 2010 Nov.; 170:1827-31.

wall, myocardial infarction and death. These fractured shards may also become too embedded in tissue or migrate to locations, such as the heart and lungs, where those shards are too dangerous to remove. These patients, like Plaintiff, are exposed to a lifetime of future risks due to the high failure and complication rates with this device.

64. The Recovery Filter similarly poses a high risk of tilting and perforating the vena cava walls. When such failures occur, the device can perforate the aorta, duodenum, small bowel, ureter, pancreas, spine, and other organs/structures/vessels - which may lead to numerous significant problems including death. Further, given the risks of injury in attempting to remove devices that have perforated the vena cava, the device may be irremovable. Thus, these patients are faced not only with an injury that cannot be fixed but with a lifetime of future additional risk due to the high failure and complication rates with this device.

65. The Recovery filter failures described above occur at a substantially higher rate than with other IVC filters.

66. Soon after the Recovery filter's introduction to the market, Bard began receiving large numbers of adverse event reports from healthcare providers. The adverse event reports ("AERs") associated with IVC filter devices demonstrates that Bard's IVC filters are far more prone to device failure then are other similar devices. A review of the FDA MAUDE database from the years 2004-2008 reveals data to establish that Bard's IVC filters are responsible for the following percentages of all AERs:

a. 50% of all adverse events

b. 64% of all occurrences of migration of the device

c. 69% of all occurrences of vena cava wall perforation

d. 70% of all occurrences of filter fracture.

67. These failures are attributable, in part, to the fact that the Recovery filter was not adequately designed to be able to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

68. In addition to design defects, the Recovery filter suffers from manufacturing defects. These manufacturing defects include, but are not limited to, the existence of "draw markings" and circumferential grinding markings on the exterior of the surface of the device. The presence of these draw markings and/or circumferential grinding markings further compromises the structural integrity of the device while *in vivo*. In particular, the Recovery filter is prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the device. Put simply, the Recovery filter is not of sufficient strength to withstand normal placement within the human body. The presence of the aforementioned exterior manufacturing defects makes the device more susceptible to failure.

69. Bard knew that no clinical testing, such as animal studies or simulated use tests, was conducted to determine whether the Recovery filter would perform safely once implanted in the human body and subjected to normal *in vivo* stresses.

70. Soon after the Recovery filter's introduction to the market in 2003, Bard began receiving large numbers of AERs from healthcare providers reporting that the Recovery filter was fracturing post-implantation and that fractured pieces and/or the entire device were migrating throughout the human body, including to the heart and lungs. Bard also received large numbers of AERs reporting that the Recovery filter was found to have excessively tilted and/or perforated the inferior vena cava post-implantation. These failures were often associated with reports of severe patient injuries such as:

a. Death;

b. Hemorrhage;

c. Cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);

d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;

e. Severe and persistent pain;

f. Thrombosis and occlusion of the IVC; and

g. Perforations of tissue, vessels and organs.

71. Within the first year of full market release of the Recovery filter, Bard and BPV received at least 32 AERs reporting that the Recovery Filter had fractured *in vivo* and at least 22 AERs reporting that the entire device had migrated *in vivo*. Of the 22 reported migration failures, at least nine (9) were reported to have been associated with a patient death.

72. From 2003 through September 2005, Bard received ever growing numbers of AERs reporting the above described failures and patient injuries. Bard knew or should have known that the failure rates associated with the Recovery filter were substantially higher than other similar products on the market, yet Bard failed to warn consumers of this unreasonably dangerous device.

73. Bard began investigating these failures in 2004, creating Failure Investigation Reports and Remedial Action Plans, but each time Bard reviewed a migration, fracture, or death, it was unable to determine the root cause. Thus, it never understood how or why these failures were happening.

74. Nonetheless, in late 2004 or early 2005 Bard, without knowing why the failures were happening (and thus what design changes were necessary to prevent them) and without notifying consumers of the design and manufacturing flaws inherent in the Recovery filter, began to make design changes to the Recovery in an attempt to correct those flaws. But, as with its design of the Recovery filter, Bard failed to appreciate how the failures were caused and how to create a design to reduce or eliminate them; further, Bard again failed to adequately test the remodeled Recovery to ensure that it was safe for permanent implantation.

75. The second generation of Bard's filter is known as the G2 filter; G2 is shorthand for "second generation" Recovery Filter. Once Bard obtained FDA approval to market G2 in and around August 2005, Bard and BPV quietly stopped marketing the Recovery filter. Bard failed, however, to make any effort to notify

consumers of the risk inherent in the use of the Recovery filter or to recall the remaining devices on hospital shelves.

The G2 and G2 Express Filters

76. In 2005, Bard made several design changes to its first-generation retrievable filter, Recovery Filter, in an attempt to fix its design flaws. The second-generation Recovery filter is called the G2.

77. As with the Recovery filter, Bard's design and testing of the G2 was significantly inadequate. For example, Bard substantially widened the base of the filter. This change was an immediate and reactionary response to the migrations of the Recovery filter to patients' hearts and related deaths. But, Bard failed to do any testing to determine what impact that change would have on the filter's safety and performance. Particularly, Bard failed to test to determine if the change would impact the filter's likelihood of tilting, perforating the IVC, or fracturing. Similarly, it again failed to test to determine how the filter would perform under foreseeable worst-case conditions.

78. And, when the filter failed some of Bard's internal test standards, including that it perform as well as or better than the SNF, Bard lowered the standard (to be better than the poor performing Recovery) rather than fix the issue and improve the G2's actual performance.

79. On August 10, 2005, Bard submitted a Section 510(k) premarket notification of intent to market the G2 filter for the prevention of recurrent pulmonary embolism via permanent placement in the inferior vena cava. Bard cited the Recovery filter as the substantially equivalent predicate device, substantially lowering the bar from the SNF, which had served as the Recovery's predicate. Bard stated that the differences between the Recovery filter and the G2 filter were primarily dimensional and no material changes or additional components were added.

80. On August 29, 2005, the FDA cleared the G2 filter for the same intended uses as the Recovery filter, except that the G2 was not cleared for retrievable use.[5]

81. Even after the redesigned G2 filter was cleared for use, Bard failed to take any steps to recall the Recovery filter and/or to notify consumers that the failure rates associated with the Recovery filter were substantially higher than other similar products on the market.

82. Bard marketed the G2 Filter as having "enhanced fracture resistance," "improved centering," and "increased migration resistance." Despite these claims, however, Bard failed to ensure that the changes made to the G2 filter were sufficient to cure the defective and unreasonably dangerous nature of the device. As a result, the G2 filter shares the same defects and health risks as its predicate device.

83. Moreover, as with its predecessor Recovery filter, Bard failed to conduct adequate clinical and bench testing to ensure that the G2 filter would perform safely and effectively once implanted in the human body.

84. Also, like its predecessor, the Recovery Filter, in addition to design defects, the G2 Filter suffers from manufacturing defects. These manufacturing defects include, but are not limited to, the existence of "draw markings" and circumferential grinding markings on the exterior of the surface of the device. The presence of these draw markings and/or circumferential grinding markings further compromises the structural integrity of the G2 Filter while *in vivo*. In particular, the G2 Filter is prone to fail at or near the location of draw markings/ circumferential grinding markings on the struts of the device. Put simply, the G2 Filter is not of sufficient strength to withstand normal placement within the human body. The presence of the aforementioned exterior manufacturing defects makes the device more susceptible to fatigue failure.

[5] The FDA did not clear the G2 filter to be used as a retrievable filter until January 15, 2008.

85. The G2 filter's design causes it to be of insufficient integrity and strength to withstand normal *in vivo* body stresses within the human body so as to resist fracturing, migrating, tilting, and/or perforating the IVC.

86. After its full market release, Bard conducted a clinical trial of the G2 filter. Like the Recovery trial, this was not a trial designed to determine the filter's long-term safety and effectiveness. Instead, the study was designed to determine the ability to retrieve the G2 in order to obtain a retrievability indication for the then permanent-only device. In that study, the G2, like the Recovery, suffered significant device failures, including migration, fracture, tilt, and perforation, in a limited patient pool of 83 patients. And, the filter demonstrated a new failure: migrating away from the heart.

87. Also, like its predecessor, in addition to design defects, the G2 filter suffers from manufacturing defects. These manufacturing defects include, but are not limited to, the existence of "draw markings" and circumferential grinding markings on the exterior of the surface of the device. The presence of these draw markings and/or circumferential grinding markings further compromises the structural integrity of the G2 filter while *in vivo*. In particular, the G2 filter is prone to fail at or near the location of draw markings/ circumferential grinding markings on the struts of the device. Put simply, the G2 filter is not of sufficient strength to withstand normal placement within the human body. The presence of the aforementioned exterior manufacturing defects makes the device more susceptible to fatigue failure.

88. As with the Recovery filter, after full market release, Bard immediately began receiving large numbers of AERs reporting that the G2 filter was, *inter alia*, fracturing, migrating, excessively tilting, and perforating the vena cava once implanted. These failures were again often associated with reports of severe patient injuries such as:

a. death;

b. hemorrhage;

c. cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);

d. cardiac arrhythmia and other symptoms similar to myocardial infarction;

e. severe and persistent pain;

f. thrombosis and occlusion of the IVC; and

g. perforations of tissue, vessels and organs.

89. Bard represents the fracture rate of the G2 filter to be 1.2 percent. Based upon a review of the data available in the public domain (including the FDA MAUDE database statistics and the published medical literature), this representation does not accurately reflect the true fracture rate for the G2 Filter.

90. As with the Recovery® filter, Bard was aware of clinical data showing that the G2® filter was not the substantial equivalent of its predecessor SNF device, requiring immediate recall of the adulterated and misbranded product.

91. On December 27, 2005, Bard's Medical Affairs Director sent an email questioning why Bard was even selling the modified version of the Recovery® filter, when Bard's SNF had few complaints associated with it which further confirms the misbranded and adulterated nature of the device, requiring corrective action, including recall.

92. A review of the MAUDE database from the years 2004-2008 reveals data to establish that the Bard's IVC filters (including the G2 Filter) are responsible for the majority of all IVC-filter reported adverse events.

93. Bard's next iteration of its permanent-but-retrievable filter was the G2 Express filter. The only design change from the G2 filter to the G2 Express filter was the addition of a snare tip at the apex of the filter to assist in its retrieval. The change had no substantive change to the performance or safety of the filter. Again, Bard failed to test the G2 Express for long-term (permanent) safety

94. The FDA cleared the G2 Express filter on July 30, 2008. The only significant difference between this filter and the G2 was a new snare tip which was designed in an effort to optimize retrieval. Bard launched and began marketing the G2 Express in August 2008. The G2 and the G2 Express are the same filter, from a design standpoint, and share the same defects and complications.

95. The G2x filter was cleared by the FDA on October 31, 2008. As with the G2 Express, the G2x had no significant design difference between it and the G2 filter (or G2 Express). Bard launched the G2x filter in January 2009. The G2, G2 Express, and the G2x are the same filter, from a design standpoint, and share the same defects and complications.

96. Upon information and belief, Plaintiff alleges that as early as 2003, Bard was aware and had knowledge of the fact that the Recovery filter was defective and unreasonably dangerous and was causing injury and death to patients who had received it. Similarly, Bard was aware as early as 2005 that the G2 filter family was defective and unreasonably dangerous and was causing injury and death to patients who had received it. And due to the similarities in design, Bard should have known that the G2 Express and G2x were just as dangerous and defective.

97. Data establishes that the failure rate of the G2, G2 Express, and G2x filters was/is exceedingly higher than the rate that Bard have in the past, and currently continue to publish to the medical community, members of the public. Further, Bard and BPV are aware or should have been aware that the G2, G2 Express, and G2x filters have a substantially higher failure rate than other similar products on the market, yet they have failed to warn consumers of this fact.

98. Upon information and belief, from the time the G2 filter became available on the market, the Bard embarked on an aggressive campaign of "off label marketing" concerning the G2 filter. This included representations made to physicians, healthcare professionals, and other members of the medical community

that the G2 filter was safe and effective for retrievable use prior to the FDA approving the G2 filter for retrievable use.

99. Despite having knowledge as early as 2005 of the unreasonably dangerous and defective nature of the product, Bard consciously disregarded the known risks and continued to actively market and offer for sale the G2, G2 Express, and G2x filters.

The Eclipse Filter

100. In response to the complications associated with the G2, G2 Express, and G2x filters along with a negative image in the marketplace for those filters, Bard decided to electropolish the filter and change its name to the Eclipse filter.

101. Bard recognized that electropolishing was fairly standard in the medical-device market and by making purely cosmetic changes to the G2X filter, it could rename and market the filter to avoid the "baggage" associated with the G2 filter.

102. The Eclipse filter was cleared by the FDA on January 14, 2010. The Eclipse filter was identical to the G2/G2X filters except that the filter was electropolished and tinted blue. The Eclipse filter continued to share the same design defects and complications associated with the Recovery, G2, G2 Express, and G2x filters due to the fact that the Eclipse design was based on its predecessors.

103. Bard launched the Eclipse filter in 2010. Soon thereafter, Bard began receiving similar complaints associated with the Eclipse filter as it had with the predecessor filters. Because the Eclipse is based on Bard's previous filter designs, the Eclipse filter shares the same or similar design and manufacturing defects as Bard's previous filters and suffers from the same complications and defects.

104. Bard was aware of the defective nature of the Eclipse filter before it hit the market, but did not discontinue sales until 2015.

The Meridian Filter

105. In an effort to address one recurring failure of the G2/G2X/Eclipse filters, Bard added "caudal" anchors to the filter and renamed it the Meridian. Caudal anchors are hooks added to the legs that point downward in an effort to keep the filter from moving

106. The Meridian filter was cleared by the FDA on August 24, 2011. The Meridian filter has the same defective design platform as Bard's predecessor filters, but added, in pertinent part, caudal migration anchors. The Meridian filter was the first Bard filter to add caudal anchors, despite Bard being aware since late 2005 of the need for caudal anchors to decrease tilt, caudal migration, perforation, and fracture. Despite awareness of the need to correct the problems its filters had with stability in the IVC and caudal migration, Bard waited 5 years before attempting to correct this issue with the Meridian filter.

107. The Meridian filter continued to share the same design defects and complications associated with the Recovery and G2/G2X/Eclipse filters due to the fact that the Meridian was the same filter with the same core design. Soon after launching the Meridian, Bard began receiving similar complaints associated with the Meridian filter as it had with the predecessor filters. Because the Meridian is the same as Bard's previous filter designs, the Meridian filter shares the same or similar design and manufacturing defects as Bard's previous filters and causes the same complications and defects.

108. Bard was aware of the defective nature of the Meridian before it hit the market.

The Denali Filter

109. Bard began developing another design of the permanent-but-retrievable IVC filter in 2009—at the same time it was rebranding the G2/G2X as the Eclipse and Meridian. Bard called that filter "Denali" and purported to make it to address the ongoing failures of the Recovery/G2/G2X/Eclipse/Meridian filter.

Unfortunately, the "new" design of the Denali was essentially the same design as the Recovery/G2/G2X/Eclipse/Meridian filter: a conical design with six arm struts and six leg struts that connect to the IVC. Thus, although the angles are a bit different at different points, the design of the Denali is the same as Bard's permanent-but-retrievable filters.

110. The Denali filter is also made of NITINOL, is electropolished like the Eclipse, and has caudal anchors like the Meridian. The one significant change that Bard made was that the NITINOL wires used in the Denali filter are electropolished prior to forming the filter.

111. Bard represented to the FDA that the Denali was the substantial equivalent of the Eclipse filter, again bypassing formal pre-market FDA approval and instead utilizing the 510(k) process.

112. Based on Bard's representations, the FDA cleared the Denali filter for sale in the U.S. on May 15, 2013.

113. As with the each earlier iteration of Bard's permanent-but-retrievable filter, soon after its introduction to the market, Bard received reports that the Denali filters were fracturing, perforating, migrating, causing extreme thrombosis and/or tilting in the patients in which they were implanted.

114. The Denali filter was likewise plagued with the same manufacturing and design defects that were causing damage to the general public in Bard's predecessor retrievable filter family.

115. At all times material hereto from the design phase, testing and manufacture of the iterations of the filter (Recovery through Denali), Bard lacked a thorough understanding of dynamics of caval anatomy that impacted testing methods.

116. At this time, all Bard IVC filters contain the same or substantially similar defects resulting in the same or substantially similar mechanism of injury to patients and their decedents.

117. At this time, all Bard IVC filters are misbranded and adulterated by

virtue of them failing to be the substantial equivalent of their predecessor devices, all of which were required to be as safe and effective as the original predicate device, the SNF, and none were/are, making them subject to corrective action, including recall, in the interest of patient safety. The use of each of these subject devices was inappropriate and illegal since each was being marketed while adulterated and misbranded for failing, among other things, to be as safe and effective as the originating predicate device, SNF.

118. At all relevant times, safer and more efficacious designs exist for this product as well as reasonable treatment alternatives.

Outrageous Conduct

119. Bard's conduct as alleged in this Complaint constitutes willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Plaintiff and the community at large. Bard had actual knowledge of the dangers presented by the Filter, yet consciously failed to act reasonably to:

a. Inform or warn Plaintiff, Plaintiff's physicians, or the public at large of these dangers;

b. Establish and maintain an adequate quality and post-market surveillance system; and

c. Recall the Filter from the market.

120. Plaintiff further alleges that Bard acted in willful, wanton, gross, and total disregard for the health and safety of the users or consumers of the Filter, when acting to serve its own interests, it knowingly and consciously disregarded the substantial risk that its product might kill or significantly harm patients, by consciously pursuing a course of conduct knowing it created a substantial risk of significant harm to other persons.

121. The failures of the Filter are attributable, in part, to the fact that the Filter was designed so as to be unable to withstand the normal long-term anatomical and physiological loading cycles exerted *in vivo*.

What Happens When An IVC Filter Fails?

122. The failure (fracture, migration, perforation, irretrievability, extreme thrombosis, etc.) of the Filter leads to a number of different, and potentially fatal, complications. These complications include, but are not limited to:

a. Death;

b. Hemorrhage;

c. Cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);

d. Severe and persistent pain;

e. Extreme lower body clotting and thrombosis;

f. Perforation of tissue, vessels and organs; and

g. Embolization.

Specific Factual Allegations As To Plaintiff

123. On or about August 29, 2006, Plaintiff underwent placement of a permanent-but-retrievable Bard G2 filter. The Filter subsequently malfunctioned by perforating the IVC and impinges on the and more than likely perforate the posterior wall of the aorta, impinges on the underlying L3-4 disc and more likely than not perforates the gonadal vein. As a further proximate result, Plaintiff has suffered and will continue to suffer significant medical expenses and pain and suffering, along with other damage. As a result, Plaintiff has suffered pain, emotional distress, and loss of enjoyment of life.

124. The Filter was designed, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold by Bard.

125. Plaintiff has incurred significant medical expenses and has endured pain and suffering, anxiety, loss of enjoyment of life, and other losses, some of which are permanent in nature.

FIRST CAUSE OF ACTION

[Strict Products Liability]

126. Plaintiff incorporates by reference all preceding paragraphs.

127. Prior to, on, and after the date the Filter was implanted in Plaintiff and at all relevant times, Defendants designed, distributed, manufactured, sold, and marketed the Filter for use in the United States.

128. At all times herein mentioned, Defendants designed, distributed, manufactured, marketed, and sold the Filter such that it was dangerous, unsafe, and defective due to design, manufacture, and lack of adequate warnings.

129. The Filter contained all of these defects when it left Defendants' possession.

130. Plaintiff is informed and believes, and on that basis alleges, that the Filter contained a manufacturing defect in that it differed from the manufacturer's design or specifications, or from other typical units of the same product line.

131. Prior to the dates on which the Filter was implanted in Plaintiff, Defendants manufactured, distributed, and sold the Filter.

132. The Filter had potential risks and side effects that were known or knowable to Defendants by the use of scientific knowledge available before, at, and after the manufacture, distribution, and sale of the Filter.

133. Defendants knew or should have known of the defective condition, characteristics, and risks associated with the Filter, as previously set forth herein.

134. Said defective conditions included, but were not limited to, the Filter posing a significant and higher risk than other similar devices of device failure (fracture, migration, tilting, extreme clotting and thrombosis, and perforation of the vena cava wall) resulting in death and/or serious injuries and that certain conditions or post-implant procedures, such as morbid obesity or open abdominal procedures, could affect the safety and integrity of the device, among other things.

135. The Filter was in a defective condition that was unreasonably and substantially dangerous to any user or ordinary consumer implanted with the Filter, such as Plaintiff when used in an intended or reasonably foreseeable way.

136. Bard IVC filters original retrievable filter design, the Recovery Filter, was determined by Bard as defective and was no longer marketed to consumers, and the G2X filter "improvement" did not prevent the likelihood of failure or injury the filters caused those implanted with the product including the Plaintiff.

137. Such ordinary consumers, including Plaintiff, would not and could not have recognized or discovered the potential risks and side effects of the Filter, as set forth herein.

138. The warnings and directions provided with the Filter by Defendants failed to adequately warn of the potential risks and side effects of the Filter, which risks were known or were reasonably scientifically knowable to Defendants, but not known or recognizable to ordinary consumers, such as Plaintiff or her treating doctors.

139. Had adequate warnings and instructions been provided such as an the increased rate of migration, fracture, or death associated with Bard filters or that these filters are not the safest filters on the market, Plaintiff would not have been implanted with Bard IVC Filters and would not have been at risk of the harmful injuries described herein. Additionally, Plaintiff and her physicians were not made aware that the Bard Simon Nitinol filter is an alternative design that would significantly reduce the risk of migration, perforation, fracture and fracture embolization without impairing the utility of the device in patients including those implanted in the Plaintiff. The Plaintiff also were not made aware that the original filter which the G2X filters designs are based on had such a high failure rate and were substantially similar in design and likelihood of failure. The Defendants failed to provide warnings of such risks and dangers to Plaintiff and her medical providers as described herein. Neither Plaintiff nor the Plaintiff's physicians knew, nor could they have learned

through the exercise of reasonable care, the risks of serious injury including but not limited to the risk of pulmonary embolism, perforation, migration, tilt, fracture, and/or death associated with and/or caused by Bards' IVC Filters.

140. Bard IVC Filters as manufactured and supplied by the Defendants are and were defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of injuries from use and acquired additional knowledge and information confirming the defective and dangerous nature of its IVC Filters, Defendants failed to provide adequate warnings to the medical community and the consumers, to whom Defendants were directly marketing and advertising; and further, Defendants continued to affirmatively promote their IVC Filters as safe and effective and as safe and effective as their predicate device.

141. The Filter was expected to and did reach Plaintiff without substantial change in its condition, labeling, or warnings as manufactured, distributed, and sold by Defendants.

142. Plaintiff and Plaintiff's physicians used the Filter in the manner in which it was intended to be used, making such use reasonably foreseeable to Defendants.

143. Defendants' lack of sufficient instructions or warnings prior to, on, and after the date Plaintiff was implanted with the Filter was a substantial factor in causing Plaintiff's injuries and damages.

144. Bard IVC Filters were and are unreasonably dangerous and defective in design or formulation for their intended use in that, when they left the hands of the manufacturers and/or supplier, they posed a risk of serious vascular and other serious injury which could have been reduced or avoided, inter alia, by the adoption of a feasible reasonable alternative design. There were safer alternative designs for the like products like the Simon Nitinol Filter ("SNF") or other manufacturer's designs.

145. Bard IVC Filters were insufficiently tested and caused harmful adverse events that outweighed any potential utility.

146. Bard IVC Filters, as manufactured and supplied, were defective due to inadequate warnings, and/or inadequate clinical trials, testing, and study, and inadequate reporting regarding the results of the clinical trials, testing and study.

147. Defendants' design, manufacture, marketing, promotion, and sale of the Filter were a substantial factor in causing Plaintiff's injuries and damages.

148. Bard IVC Filters were and are unreasonably dangerous in that, as designed, failed to perform safely when used by ordinary consumers, including Plaintiff, including when the filters were used as intended and in a reasonably foreseeable manner.

149. As a direct and proximate result of Defendants' defective design, manufacture, marketing, and sale of the Filter prior to and on the date Plaintiff used the Filter, Plaintiff suffered damages herein described.

SECOND CAUSE OF ACTION

[Negligence—Design, Manufacture, Sale]

150. Plaintiff incorporates by reference all preceding paragraphs.

151. Prior to, on, and after the date the Filter was implanted in Plaintiff, and at all relevant times, Defendants designed, tested, distributed, manufactured, advertised, sold, and marketed the Filter for use by consumers, such as Plaintiff, in the United States.

152. Prior to, on, and after the date the Filter was implanted in Plaintiff, Defendants had a duty to exercise due care and avoid unreasonable risk of harm in and about their design, testing, distribution, manufacture, advertising, sale, and marketing of the Filter.

153. At the time of design, distribution, manufacture, advertising, sale, marketing, and implantation of the Filter in Plaintiff, Defendants were aware of the following facts:

a. The Filter was designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the Filter;

b. The Filter was designed and manufactured so as to present a unreasonable risk of migration of the device and/or portions of the device;

c. The Filter was designed and manufactured so as to present a unreasonable risk of the device tilting and/or perforating the vena cava wall;

d. The Filter was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body;

e. The Filter was designed and manufactured to present a unreasonable risk of extreme clotting and IVC thrombosis;

f. The Filter would be used without inspection for defects;

g. The Filter would be used by patients with special medical conditions such as those of Plaintiff; and

h. The Filter had previously caused serious bodily injury to its users with special medical conditions such as those of Plaintiff.

154. Prior to and on the date of Plaintiff's implantation with the Filter, Defendants breached their duty of care by, but not limited to, the following:

a. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

b. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential

harm from the product exceeded the likelihood of potential harm from other devices available for the same purpose;

c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;

d. Failing to use reasonable care to warn or instruct Plaintiff, Plaintiff's physicians, or the general healthcare community about the Filter's substantially dangerous condition or about facts making the product likely to be dangerous;

e. Failing to perform reasonable pre- and post-market testing of the Filter to determine whether or not the product was safe for its intended use;

f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the Filter;

g. Advertising, marketing, and recommending the use of the Filter, while concealing and failing to disclose or to warn of the dangers known by Defendants to be connected with and inherent in the use of the Filter;

h. Representing that the Filter was safe for its intended use when, in fact, Defendants knew or should have known the product was not safe for its intended purpose;

i. Continuing manufacture and sale of the Filter with the knowledge that said product was dangerous and not reasonably safe, and failing to comply with FDA good manufacturing regulations and policy;

j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the Filter so as to avoid the risk of serious harm associated with the use of the Filter;

k. Advertising, marketing, promoting and selling the Filter for uses other than as approved and indicated in the product's label;

l. Failing to establish an adequate quality assurance program used in the manufacturing of the Filter; and

m. Failing to perform adequate evaluation and testing of the Filter where such evaluation and testing would have revealed the propensity of the Filter to cause injuries and death as described herein.

155. Defendants' conduct also violates Federal and other laws, regulations, and policies, all of which are designed to protect consumers like Plaintiff.

156. These laws include, without limitation, 18 U.S.C. §§ 2, 1001, 333(b), and 1341; 21 U.S.C. §331(a).

157. Defendants' violation of these safety statutes proscribing specific conduct constitutes negligence *per se.*

158. As a direct and legal result of the above-described negligence in design, testing, distribution, manufacture, advertising, sales, and marketing, Plaintiff sustained the injuries and damages described above.

THIRD CAUSE OF ACTION

[Negligence—Failure to Recall/Retrofit]

159. Plaintiff incorporates by reference all preceding paragraphs.

160. Prior to, on, and after the date of Plaintiff's implantation with the Filter, and at all relevant times, Defendants designed, distributed, manufactured, sold, and marketed the Filter for use by consumers such as Plaintiff in the United States.

161. Prior to, on, and after the date of Plaintiff's implantation with the Filter, and at all relevant times, Defendants knew or reasonably should have known that the

Filter and its warnings were dangerous or were likely to be dangerous when used in a reasonably foreseeable manner.

162. Prior to, on, and after the date of Plaintiff's implantation with the Filter, and at all relevant times, Defendants became aware that the defects of the Filter resulted in the Filter causing injuries similar to those Plaintiff suffered.

163. Defendants negligently and carelessly failed to recall, to retrofit, or to warn patients or physicians about the danger of the Filter prior to, on, and after the date of Plaintiff's implantation with the Filter and continue to fail to recall the device up until the present time.

164. Reasonable manufacturers and distributors under the same or similar circumstances would have recalled or retrofitted the Filter and would thereby have avoided and prevented harm to many patients, including Plaintiff.

165. As a direct and legal result of the above-described negligent failure to recall or retrofit, Plaintiff suffered the injuries described above.

FOURTH CAUSE OF ACTION

[Negligence—Failure to Warn]

166. Plaintiff incorporates by reference all preceding paragraphs.

167. Prior to, on, and after the date of Plaintiff's implantation with the Filter, and at all relevant times, Defendants designed, distributed, manufactured, sold, and marketed the Filter for use by consumers, such as Plaintiff, in the United States.

168. Prior to, on, and after the date of Plaintiff's implantation with the Filter, and at all relevant times, Defendants knew or should have known that the Filter was dangerous or was likely to be dangerous when used in a reasonably foreseeable manner. Such danger included the propensity of the Filter to cause injuries similar to those suffered by Plaintiff.

169. Prior to, on and after the date of Plaintiff's implantation with the Filter, Defendants knew or reasonably should have known that the users of the device,

including Plaintiff and Plaintiff's physicians, would not realize the dangers presented by the Filter.

170. Prior to, on, and after the date of Plaintiff's use of the Filter, Defendants negligently and carelessly failed to adequately warn of the dangers presented by the Filter and/or failed to instruct on the safe use of the Filter.

171. Reasonable manufacturers and reasonable distributors, under the same or similar circumstances as those of Defendants prior to, on, and after the date of Plaintiff's use of the Filter, would have warned of the dangers presented by the Filter, instructed on the safe use of the Filter, explained safer alternatives, such as the SNF, or instructed on the safe use of Bard IVC Filters.

172. Prior to the date of Plaintiff's use of the Filter, the Filter had already caused numerous instances of injuries similar to those suffered by Plaintiff, as well as death, as alleged herein. Defendants deliberately failed to warn of the Filter's increased propensity to cause these serious complications, or of the signs and symptoms of these complications.

173. As a direct and proximate result of Defendants' failure to warn, Plaintiff sustained the injuries and damages described above.

FIFTH CAUSE OF ACTION

[Negligence—Misrepresentation]

174. Plaintiff incorporates by reference all preceding paragraphs.

175. Prior to, on, and after the dates during which Plaintiff was implanted with the Filter, Defendants negligently and carelessly represented to Plaintiff, Plaintiff's physicians, and the general public that an important fact was true, namely that the Filter was safe, fit, and effective for use.

176. Prior to, on, and after the dates during which Plaintiff purchased and used the Filter, said representations were not true, and there was no reasonable ground for believing said representations to be true at the times said representations were made.

177. Prior to, on, and after the dates during which Plaintiff purchased and used the Filter, Defendants intended that Plaintiff, her treating physicians, and the general public would rely on said representations, which Plaintiff did reasonably do at said times.

178. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors, also knew or reasonably should have known that patients receiving Bard IVC Filters as recommended by health care professionals in reliance upon information disseminated by Bard as the manufacturer/distributor of Bard IVC Filters would be placed in peril of developing the serious, life-threatening, and life-long injuries including, but not limited to, tilting, migration, perforation, fracture, lack of efficacy, and increased risk of the development of blood clots, if the information disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

179. Defendants failed in each of these duties by misrepresenting to Plaintiff and the medical community the safety and efficacy of Bard IVC Filters and failing to correct known misstatements and misrepresentations.

180. Defendants had a duty to promptly correct material misstatements it knew others were relying upon in making healthcare decisions including but not limited to its under reporting of filter failure rates to the FDA's MAUDE database.

181. Defendants IVC Filters, including the G2, are only cleared by the 510(K) process which means that the FDA did not make a finding of the safety and efficacy of the filters.

182. As a direct and proximate result of Defendants' negligent misrepresentation, Plaintiff sustained the injuries and damages described above.

SIXTH CAUSE OF ACTION

[Breach of Express Warranty]

183. Plaintiff incorporates by reference all preceding paragraphs.

184. Prior to, on, and after the dates during which Plaintiff was implanted with the Filter, and at all relevant times, Defendants, and each of them, had knowledge of the purpose for which the Filter was to be used, and represented it to be in all respects safe, effective, and proper for such purpose.

185. At the time and place of sale, distribution and supply of the Bard IVC Filters to Plaintiff (and to other consumers and the medical community), the Defendants expressly represented and warranted in their marketing materials, both written and orally, and in the IFUs, that the Bard IVC Filters were safe, well-tolerated, efficacious, and fit for their intended purpose and were of marketable quality, that they did not produce any unwarned-of dangerous side effects, and that they were adequately tested.

186. Said warranties and representations were made to consumers, such as Plaintiff, her treating physicians and medical professionals.

187. At the time of Plaintiff's purchase from Defendants, the Bard IVC Filters were not in a merchantable condition and Defendants breached their expressed warranties, in that the filters:

a. Were designed in such a manner as to be prone to an unreasonably high incident of fracture, perforation of vessels and organs, and/or migration;

b. Were designed in such a manner so as to result in an unreasonably high incident of injury to the organs of its purchaser; and

c. Were manufactured in such a manner so that the exterior surface of the Bard Filters were inadequately, improperly and inappropriately designed causing the device to weaken and fail.

188. Plaintiff and her treating physicians relied on said warranties and representations in deciding to use the Filter.

189. Defendants, and each of them, breached the above-described express warranties and representations in that the Filter did not conform to these express warranties and representations, as the Filter was and is not safe or effective and it produces serious side effects including, among other things, the injuries sustained by the Plaintiff.

190. Prior to, on, and after the dates during which Plaintiff purchased and used the Filter, Defendants, and each of them, were put on notice of the Filter's inability to conform to these express warranties.

191. As a direct and proximate cause of Defendants' breach of express warranty, Plaintiff sustained the injuries and damages described above.

SEVENTH CAUSE OF ACTION

[Breach of Implied Warranty of Fitness for Particular Purpose]

192. Plaintiff incorporates by reference all preceding paragraphs.

193. At all relevant times, Defendants were in the business of selling the Filter.

194. Defendants breached their implied warranties as follows:

a. Defendants failed to provide the warning or instruction and/or an adequate warning or instruction which a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that its Bard IVC Filters would cause harm;

b. Defendants manufactured and/or sold their Bard IVC Filters and said filters did not conform to representations made by the Defendants when they left the Defendants' control;

c. Prior to, on, and after the dates during which Plaintiff purchased and were implanted with the Device, the Device was, among other things: not of the same quality as those other, similar IVC filters generally acceptable in the trade;

not fit for the ordinary purpose for which such IVC filters are generally used; and did not conform to the quality established by the usage of the trade;

d. Defendants manufactured and/or sold their Bard IVC Filters which were more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, and the foreseeable risks associated with the Bard Filters' design or formulation exceeded the benefits associated with that design. These defects existed at the time the products left the Defendants' control;

e. Defendants manufactured and/or sold their Bard IVC Filters when they deviated in a material way from the design specifications, formulas or performance standards or from otherwise identical units manufactured to the same design specifications, formulas, or performance standards, and these defects existed at the time the products left the Defendants' control; and

f. The Device in many instances caused or failed to prevent Pulmonary Embolisms it was created to protect against.

195. Prior to, on, and after the dates during which Plaintiff purchased and was implanted with the Filter, Defendants, and each of them, knew or had reason to know that Plaintiff and her treating physicians were relying on their skill and judgment to select or to furnish medical devices that were suitable for a relevant particular purpose, namely the prevention of injury caused by PE.

196. Prior to, on, and after the dates during which Plaintiff purchased and was implanted with the Filter, Plaintiff and her treating physicians justifiably relied on Defendants' skill and judgment.

197. Prior to, on, and after the dates during which Plaintiff purchased and was implanted with the Filter, it was in fact not suitable for the relevant particular purpose, namely prevention of injury caused by PE.

198. Prior to, on, and after the dates during which Plaintiff purchased and was implanted with the Filter, Defendants, and each of them, were put on notice of the Filter's inability to conform to these warranties.

199. Prior to, on, and after the dates during which Plaintiff purchased and was implanted with the Filter, Defendants, and each of them, were put on notice of the Filter's tendency to cause extreme clotting and IVC thrombosis – the very injury it was designed to prevent.

200. As a direct and proximate cause of Defendants' breach of said implied warranty of fitness for a particular purpose, Plaintiff sustained the injuries and damages described above.

EIGHTH CAUSE OF ACTION

[Breach of Implied Warranty of Merchantability]

201. Plaintiff incorporates by reference all preceding paragraphs.

202. Prior to implantation with the Filter, Plaintiff purchased the Filter from Defendants.

203. Prior to, on, and after the dates during which Plaintiff purchased and was implanted with the Filter, Defendants, and each of them, were in the business of selling medical devices, such as IVC filters.

204. Prior to, on, and after the dates during which Plaintiff purchased and was implanted with the Filter, the Filter was, among other things: not of the same quality as those other, similar IVC filters generally acceptable in the trade; not fit for the ordinary purpose for which such IVC filters are generally used; and did not conform to the quality established by the usage of the trade.

205. Prior to, on, and after the dates during which Plaintiff purchased and was implanted with the Filter, Defendants, and each of them, were put on notice of the Filter's inability to conform to these warranties.

206. As a direct and proximate result of Defendants' breach of said implied warranty of merchantability, Plaintiff sustained the injuries and damages described above.

NINTH CAUSE OF ACTION

[Fraud—Misrepresentation]

207. Plaintiff incorporates by reference all preceding paragraphs.

208. At all times relevant to this cause, and as detailed above, Defendants intentionally provided Plaintiff, Plaintiff's physicians, and the medical community, as well as the public at large, with false or inaccurate information, and/or omitted material information concerning the Filter, including, but not limited to, misrepresentations regarding the following topics:

a. The safety of the Filter;

b. The efficacy of the Filter;

c. The rate of failure of the Filter;

d. The pre-market testing of the Filter; and

e. The approved uses of the Filter.

209. The information distributed by Defendants to the public, the medical community, and Plaintiff was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, and instructions for use, as well as through their officers, directors, agents, and representatives.

210. These materials contained false and misleading material representations, which included: that the Filter was safe and fit when used for its intended purpose or in a reasonably foreseeable manner; that it did not pose dangerous health risks in excess of those associated with the use of other similar

devices; that any and all side effects were accurately reflected in the warnings; and that it was adequately tested to withstand normal placement within the human body.

211. Defendants made the foregoing misrepresentations knowing that they were false or without reasonable basis.

212. These materials included instructions for use and a warning document that was included in the package of the Filter that was implanted in Plaintiff.

213. Defendants' intent and purpose in making these misrepresentations was to deceive and to defraud the public and the medical community, including Plaintiff's healthcare providers; to gain the confidence of the public and the medical community, including Plaintiff's healthcare providers; to falsely assure them of the quality of the Filter and its fitness for use; and to induce the public and the medical community, including Plaintiff's healthcare providers, to request, recommend, prescribe, implant, purchase, and continue to use the Filter, all in reliance on Defendants' misrepresentations.

214. The foregoing representations and omissions by Defendants were in fact false. The Filter is not safe, fit, or effective for human use in its intended and reasonably foreseeable manner. The use of the Filter is hazardous to the user's health, and said device has a serious propensity to cause users to suffer serious injuries, including without limitation, the injuries Plaintiff suffered. Further, the Filter has a high rate of failure and injury when compared to similar devices.

215. In reliance upon the false and negligent misrepresentations and omissions made by Defendants, Plaintiff and her healthcare providers were induced to use, and did use, the Filter, thereby causing Plaintiff's injuries.

216. Defendants knew and had reason to know that Plaintiff, Plaintiff's healthcare providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by Defendants, and would not have prescribed and implanted same,

if the true facts regarding the Filter had not been concealed and misrepresented by Defendants.

217. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause death and serious injuries and damages to persons who are implanted with the Filter.

218. At the time Defendants failed to disclose and intentionally misrepresented the foregoing facts, and at the time Plaintiff used the Filter, Plaintiff and her healthcare providers were unaware of said Defendants' negligent misrepresentations and omissions.

219. Bard had a duty to disclose all adverse events to the FDA in a timely and efficient manner and did not do so, such as in 2015.

220. Plaintiff, Plaintiff's healthcare providers, and the general medical community reasonably relied upon misrepresentations and omissions made by Defendants where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the Filter.

221. As a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiff sustained the injuries and damages described above.

TENTH CAUSE OF ACTION

[Fraud—Concealment]

222. Plaintiff incorporates by reference all preceding paragraphs.

223. In marketing and selling the Filter, Defendants concealed material facts from Plaintiff and Plaintiff's healthcare providers.

224. Defendants' concealed material facts include, but are not limited to, the following:

a. That the Filter was unsafe and not fit when used for its intended purpose or in a reasonably foreseeable manner;

b. That the Filter posed dangerous health risks in excess of those associated with the use of other similar devices;

c. That there were additional side effects related to implantation and use of the Filter that were not accurately and completely reflected in the warnings associated with the Filter; and

d. That the Filter was not adequately tested to withstand normal placement within the human body.

e. Under reporting adverse event to the FDA in a timely manner.

225. Plaintiff and Plaintiff's healthcare providers were not aware of these and other facts concealed by Defendants.

226. In concealing these and other facts, Defendants intended to deceive Plaintiff and Plaintiff's healthcare providers.

227. Plaintiff and Plaintiff's healthcare providers reasonably and justifiably relied on Defendants' representations. Plaintiff and Plaintiff's healthcare providers were ignorant of and could not reasonably discover the facts Bard fraudulently concealed and reasonably and justifiably relied on Bard's representations concerning the supposed safety and efficacy of Bard IVC Filters.

228. As a direct and proximate result of Defendants' concealment, Plaintiff sustained the injuries and damages described above.

Punitive Damages Allegations

229. Plaintiff hereby incorporates by reference all preceding paragraphs.

230. Upon information and belief, Plaintiff alleges that, as early as 2003, Bard was aware and had knowledge of the fact that the predicates to the Filter, including the G2 filter, were defective and unreasonably dangerous and were causing injury and death to patients who had received it.

231. Data establishes that the failure rates of the Filter and its precursors are and were much higher than the rate Bard had in the past and currently continue to publish to the medical community and members of the public. Defendants knew this and continued to sell the Filter.

232. Bard also was aware or should have been aware that the Filter and its precursors had a substantially higher failure rate than other similar products on the market, yet Defendants have failed to warn consumers about the Filter.

233. The conduct of Bard as alleged in this Complaint constitutes willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Plaintiff.

234. Bard had actual knowledge of the dangers presented by the Filter, yet consciously failed to act reasonably to:

a. Inform or warn Plaintiff, Plaintiff's physicians, or the public at large of these dangers; to remove the Filter from the inventory of the facility where Plaintiff was implanted; and,

b. Establish and maintain an adequate quality and post-market surveillance system.

235. Despite having knowledge of the unreasonably dangerous and defective nature of the Filter, Bard consciously disregarded the known and substantial risks of death and injury and continued to actively market and offer for sale the Filter.

236. Plaintiff further alleges that Defendants acted in willful, wanton, gross, and total disregard for the health and safety of the users or consumers of the Filter, acted to serve their own interests (some of them pecuniary), and consciously disregarded the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others.

237. As a result, Plaintiff is entitled to an award of punitive damages to punish Defendants and deter similar conduct in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants as follows:

1. For general (non-economic) damages according to proof at the time of trial, including pain and suffering;

2. For special (economic) damages according to proof at the time of trial, including payment of past and future medical expenses, lost wages and loss of income potential;

3. For punitive damages, sufficient to punish and deter Defendants;

4. For prejudgment interest as permitted by law;

5. For costs of suit incurred herein as permitted by law; and

6. For such other and further relief as this Court may deem proper.

DATED this day of 2020.

TAUTFEST BOND, PLLC

By: _____

Attorney for Plaintiff